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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,035

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Jan Skansen

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6755

466

7590

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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,035	<b>Applicant(s)</b> SKANSEN ET AL.	
	<b>Examiner</b> SHEFALI D. PATEL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006 and 15 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 19-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/15/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file: 0303387-5, filed in Sweden on December 17, 2003.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 recites the limitations “said control means” and “the pumping means”. There is insufficient antecedent basis for these limitations in the claim, as said limitations are not present in claim 28, from which claim 37 depends. Claim 37 may more properly depend from claim 36, in which the limitations “a control means” and “a pumping means” are first introduced.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

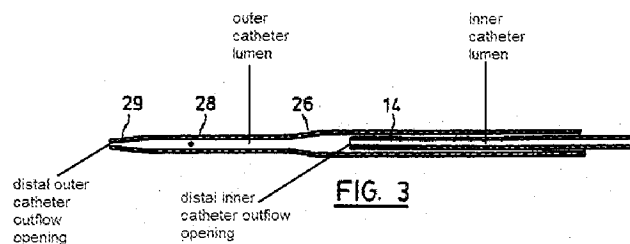
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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 19-22 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Uldall (US 4,493,696).

In regards to claim 19, Uldall teaches a catheter device (Figures 1-5, cannula [10]) comprising:

- a. an outer catheter (outer member [12]) provided with one outer catheter lumen (labeled in Figure 3 below) with a distal outer catheter outflow opening (end aperture [30]) (Figures 1-5)
- b. an inner catheter (inner member [14]) provided with at least one inner catheter lumen (labeled in Figure 3 below) with at least one distal inner catheter outflow opening (labeled in Figure 3 below)
- c. said inner catheter [14] is adapted to be detachably arranged in said outer catheter lumen (column 5, lines 6-7), characterized in that when the catheter device [10] is adapted to be used for administration of substances to a patient, said inner catheter outflow opening is located proximally said outer catheter outflow opening (Figures 3-5).



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In regards to claim 20, Uldall teaches that said inner catheter [14] is coaxially arranged with regard to said outer catheter [12] (Figures 3-4).

In regards to claim 21, Uldall teaches that at least one substance is active (column 5, lines 54-57).

In regards to claim 22, Uldall teaches that said active substance is administered by said inner catheter [14] (Figure 5) (column 5, lines 54-57).

In regards to claim 32, Uldall teaches that each lumen (*labeled in Figure 3 above*) in the inner catheter [14] administers an active substance (Figure 5) (column 5, lines 54-57)

In regards to claim 33, Uldall teaches that all surfaces in contact with the active substance in the catheter device [10] are made of tetrofluoro polyethylene (column 3, lines 16-24).

In regards to claim 34, Uldall teaches that the volume of a liquid pulse of the substance is approximately the same as the volume defined in said outer catheter lumen (*labeled in Figure 3 above*) between the inner catheter outflow opening (*labeled in Figure 3 above*) and the outer catheter outflow opening [30] (Figure 5).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 23, 24, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uldall, as applied to claim 19, and further in view of Griego et al (US 6,663,596).

In regards to claim 23, Uldall is silent about whether said substance is administered as a pulsed flow sequence of substance comprising a predetermined number of liquid pulses, wherein each liquid pulse is a predetermined volume of the substance. Griego et al teaches a catheter device (Figure 10a-10b, delivery system [16]) wherein a substance (second material, *not referenced*) is administered as a pulsed flow sequence of substance with a control system [298] controlling the number of liquid pulses from a reservoir [296] connected to a pump [283]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a pulsed flow sequence of substance with a control system, reservoir, and pump, as taught by Griego et al, with the catheter device of Uldall, as such will enable the user to control and monitor the amount of substance infused into the patient based on computerized control of the pressure and material flow by a control system (column 8, lines 19-43).

In regards to claim 24, Uldall is silent about whether said outer [12] and inner [14] catheters comprise at their respective proximal ends first connection means for connection to an external pump device having one or more reservoirs for substances and flushing liquids. Griego teaches a catheter device (Figure 10a-10b, delivery system [16]) with outer and inner catheters (first elongated member [100] and second elongated member [200]) having first connection means (connection ports [170][270]) at their respective proximal ends for connection to external pump devices (first pump [183] and second pump [283]) having reservoirs (reservoirs [196][296]) for substances and flushing liquids (first and second materials, *not referenced*). It would have been obvious to a person having ordinary skill in the art at the time the invention was

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made to incorporate first connection means, as taught by Griego et al, onto the proximal ends of the inner and outer catheters, of the catheter device of Uldall, as the pumps/reservoirs, connected at the first connection means, will provide an efficient means for controlling pressure and effecting substance delivery through the catheter device (column 8, lines 19-43).

In regards to claim 36, Uldall teaches an infusion system (Figures 1-5) comprising a catheter device [10] according to claim 19 (*as shown above in the rejection of claim 19 under Uldall*). However, Uldall does not teach that the infusion system further comprises a pumping means, a reservoir means, and a control means. Griego et al teaches an infusion system (Figure 10a-10b) with a catheter device (delivery system [16]), a pumping means (first pump [183] and second pump [283]), a reservoir means (reservoirs [196][296]), and a control means (control system [298]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a pumping means, a reservoir means, and a control means, as taught by Griego et al, with the infusion system of Uldall, as such will enable the user to control and monitor the amount of substances infused into the patient based on computerized control of the pressure and material flow by a control system (column 8, lines 19-43).

8. Claims 25-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uldall, as applied to claim 19 above, and further in view of Balbierz et al (US 5,156,596).

In regards to claim 25, Uldall teaches that said catheter device [10] is provided with a second connector means (junction piece [18]); however, Uldall does not teach that the second connector means [18] is responsible for detachably arranging the inner catheter [14] within the

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outer catheter [12]. Balbierz et al teaches a catheter device (Figures 3-5, catheter assembly [10]) with a second connector means (Luer locking mechanism [66]) for detachably arranging an inner catheter [52] within an outer catheter [28] (column 7, lines 65-68 to column 8, lines 1-3). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply second connecting means, as taught by Balbierz et al, to both the inner catheter and the outer catheter, of the catheter device of Uldall, as such will effect a stable connection between the inner catheter and the outer catheter during the use of the catheter device until the inner catheter is to be detached and replaced by another inner catheter.

In regards to claim 26, in a modified catheter device of Uldall and Balbierz et al, Uldall teaches that said second connector means [18] is partly integrated in a Y-connection (Figures 1-2).

In regards to claims 27-29, in a modified catheter device of Uldall and Balbierz et al, Uldall does not teach that the second connector means [18] is responsible for detachably arranging the inner catheter [14] within the outer catheter [12]. Balbierz et al teaches a second connector means (Luer locking mechanism [66]) which includes a first fastening means (region [46]) at the proximal end of an inner catheter (inner cannula [52]) that cooperates with a second fastening means (portion [24]) integrated with an opening in the outer catheter (outer cannula [28]) (column 7, lines 54-68 to column 8, lines 1-3). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to apply second connecting means (first fastening means and second fastening means), as taught by Balbierz et al, to both the inner catheter and the outer catheter, of the modified catheter device of Uldall and Balbierz et al, as such will effect a stable connection between the inner catheter and the outer catheter during



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the use of the catheter device until the inner catheter is to be detached and replaced by another inner catheter.

In regards to claim 31, Uldall does not teach that the inner catheter [14] comprises two lumen, as Uldall only teaches one lumen (Figures 3-5). Balbierz et al teaches a catheter device (Figure 11) comprising an inner catheter (inner cannula [52]) with two lumen (passages [90][92]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the inner catheter, of the catheter device of Uldall, to have two lumen, as taught by Balbierz et al, as two lumen will allow the inner catheter to deliver two different substances to the patient, for example, if so desired by the user.

9. Claims 30 and 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uldall, as applied to claim 19 above, and further in view of Porter (US 2003/0216685).

In regards to claims 30 and 35, Uldall does not teach that a liquid pulse of the active substance through the inner catheter lumen is followed in time sequence by a liquid pulse of a flushing liquid applied through the outer catheter lumen, since Uldall does not teach that the outer catheter supplies a flushing liquid. Porter teaches a catheter device (Figure 1, catheter device [10]) with a two-step flow procedure in which a liquid pulse of an active substance (second fluid component [14]) through the inner catheter lumen (lumen [34]) of an inner catheter (inner tubular element [22]) is followed in time sequence by a liquid pulse of a flushing liquid (first fluid component [12]) applied through the outer catheter lumen (lumen [28]) of an outer catheter (outer tubular element [20]) (paragraph [0061]). It would have been obvious to a person

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having ordinary skill in the art at the time the invention was made to apply a two-step flow procedure, as taught by Porter, to the catheter device of Uldall, as such will improve the homogeneity of a mixture of the active substance and the flushing liquid by delivering the two types of liquid pulses in alternate and successive pulses (paragraph [0061]). Also, the flushing liquid will improve the flowability of the active substance within the patient's body.

10. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Uldall and Balbierz et al, as applied to claim 28 above, and further in view of Griego et al.

In regards to claim 37, in a modified catheter device of Uldall and Balbierz et al, Uldall does not teach a control means or a pumping means. Griego et al teaches a catheter device (Figures 10a-10b, delivery system [16]) with a pumping means (first pump [183] and second pump [283]) and a control means (control system [298]), wherein the control means [298] controls the pumping means [183][283] such that a preset sequence of liquid pulses to be dispensed is obtained (column 8, lines 19-43). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to incorporate a pumping means and a control means, as taught by Griego et al, with the modified catheter device of Uldall and Balbierz et al, as such will enable the user to control and monitor the amount of substances infused into the patient based on computerized control of the pressure and material flow by a control system (column 8, lines 19-43).

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Lenker (US 2005/0113799), Rogers et al (US 2006/0155258), Leone et al (US

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5,885,244), Fulton (US 6,852,097), Whalen et al (US 5,344,395), Gonon (US 6,423,028), Vaillancourt (US 4,318,402).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

08/20/2008

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

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